# Alternative Strategies for Medicare Payment of Outpatient Prescription Drugs—Part B and Beyond

*Patricia M. Danzon, PhD; Gail R. Wilensky, PhD; and Kathleen E. Means, BS*

Reimbursement options for pharmaceuticals reimbursed under Medicare Part B (physician-dispensed drugs) are changing and the new comprehensive Part D Medicare outpatient drug benefit brings further changes. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) replaces traditional policy, of reimbursing Part B drugs at 95% of average wholesale price (AWP, a list price), with a percentage markup over the manufacturer's average selling price; in 2005 an indirect competitive procurement option will be introduced. In our view, although AWP-based reimbursement has been fraught with problems in the past, these could be fixed by constraining growth in AWP and periodically adjusting the discount off AWP. With these revisions, an AWP-based rule would preserve incentives for competitive discounting and deliver savings to Medicare. By contrast, basing Medicare reimbursement on a manufacturer's average selling price undermines incentives for discounting and, like any cost-based reimbursement rule, may result in higher prices to both public and private purchasers. Indirect competitive procurement for drugs alone, using specialty pharmacies, pharmacy benefit managers, or prescription drug plans, is unlikely to constrain costs to acceptable levels unless contractors retain flexibility to use standard benefit management tools. Folding Part B and Part D into comprehensive contracting with health plans for full health services is likely to offer the most efficient approach to managing the drug benefit.

*(Am J Manag Care. 2005;11:173-180)*

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) radically changed coverage and reimbursement for outpatient pharmaceuticals. The MMA established Medicare Part D, which provides comprehensive outpatient prescription drug coverage for seniors, starting in 2006. This benefit is to be administered by stand-alone private prescription drug plans (PDPs), whose role is to negotiate drug discounts and process claims on behalf of the government. More immediately, MMA changed the rules for reimbursement of physician-dispensed drugs, which are already covered under Medicare Part B. Specifically, starting in January 1, 2004, reimbursement for most Part B drugs was reduced from 95% of their current average wholesale price (AWP) to 85% of their AWP on April 1, 2003. Beginning in January 1, 2005, reimbursement for single-source (mostly on-patent originator) drugs is 106% of their average selling price (ASP) or wholesale acquisition cost (WAC), whichever is lower. Reimbursement could be lower if the widely available market price is at least 5% less than the ASP. For multiple-source drugs (generics and off-patent brands), reimbursement is based on the ASP subject to a maximum allowable charge (MAC) limit. (The MAC is based on the ASP of a low-priced product in the molecule.) The ASP is intended to represent the volume-weighted, average manufacturer selling price net of rebates and discounts, to all purchasers excluding Medicaid and federal purchasers.

Beginning in 2006, Centers for Medicare & Medicaid Services (CMS) will begin a competitive acquisition program as an option for dispensing physicians. The organization will select, by competitive bid, at least 2 contractors in each area to be responsible for negotiating drug prices with manufacturers and delivering drugs to physicians. Physicians may opt to continue their own drug purchasing, with the ASP/WAC reimbursement in place for 2005, or they may obtain Part B drugs from 1 of the contractors in their area. Under this option, physicians will no longer acquire Part B drugs from manufacturers or seek reimbursement from CMS; these functions will be assumed by contractors, along with any associated profit or loss. Many details of the competitive acquisition program remain to be determined, including defining the geographic areas and setting standards for quality, access, financial stability, and solvency. Under the legislation, CMS is to make recommendations

From the Departments of Health Care Systems and Insurance and Risk Management, The Wharton School, University of Pennsylvania, Philadelphia, Pa (PMD); Project HOPE, Bethesda, Md (GRW); and Patton Boggs LLP, Washington, DC (KEM).

This research was supported by a grant from Aventis Pharmaceuticals, Bridgewater, NJ. The views expressed are those of the authors and do not necessarily represent the views of the research sponsor.

Address correspondence to: Patricia M. Danzon, PhD, Chairperson, Department of Health Care Systems, The Wharton School, University of Pennsylvania, 204 Colonial Penn Center 3641 Locust Walk Philadelphia, PA 19104-6218. E-mail: danzon@wharton.upenn.edu.

to Congress by January 2005 on whether Part B drugs should become part of the Part D benefit, but new legislation would be required in order for that change to occur.

The efficient design of Medicare payment policies for drugs is a critical issue, given the fiscal pressure implied by this benefit and its potential effect on private sector payers, the pharmaceutical industry, and ultimately consumers. The elderly, who currently represent about 12% of the US population, consume about 40% of pharmaceuticals sold in the United States; this share is expected to increase as the US population ages. Although more than 78% of seniors already have some drug coverage,[1] the Medicare drug benefit expands and consolidates this coverage, making Medicare the dominant payer for pharmaceuticals in the United States. Thus Medicare's reimbursement strategies will influence pharmaceutical prices and profitability, and ultimately incentives for research and development (R&D) and the availability of new drugs for consumers worldwide.

Here we review Medicare's payment options for drugs, comparing the effects of alternative administered pricing rules—specifically, rules based on list versus transactions price—and alternative competitive strategies, in the context of the economic realities of pharmaceutical pricing. We evaluated the effects of these various policies for Part B drugs, because reimbursement rules are already defined and Medicare is already the dominant payer. We draw conclusions from the Part B experience for the larger Part D benefit and for state Medicaid and private payers.

## MEDICARE DRUG REIMBURSEMENT POLICY BEFORE THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND MODERNIZATION ACT OF 2003

Several recent reviews of Medicare's Part B drug policy have been excellent.[2,3] Here we provide a brief historical perspective, as background to the discussion of future reimbursement options.

Medicare Part B traditionally covers outpatient drugs that are related to a physician's service or a covered medical device and some immunosuppressive drugs. About 75% of current reimbursement is paid to physicians for drugs that they acquire, primarily chemotherapy, other cancer treatments, and other infusion drugs. In 2002, Medicare spent about $8.4 billion on these drugs, up from $6.5 billion in 2001 and $4 billion in 1999 (Bill London, personal communication, February 2, 2005). The almost 3-fold increase between 1998 and 2002 implies an average annual growth of 27%, far exceeding the annual growth rate of private-sector outpatient drug spending.

Prior to 2004, Medicare's payment for Part B drugs was set at the AWP minus 5%. The AWP as a concept for reimbursement originated in the 1960s in response to a wide variety of "cost" prices used by wholesalers, direct-selling manufacturers, specialty wholesalers, and pharmacies. Led by Medi-Cal (California's Medicaid program), AWP was adopted as a "standard cost definition that would reflect what wholesalers normally charged for the drug." Starting in 1969, Medi-Cal paid pharmacies AWP plus a flat dispensing fee to cover the pharmacist's professional service. The initial problem of not having a listing of such prices was resolved when first the Red Book and then the Blue Book starting publishing AWPs as reported by drug wholesalers.[4]

In 1991, the Health Care Financing Administration (HCFA, the predecessor agency to CMS) announced that outpatient drugs would be reimbursed at the lower of AWP or the estimated acquisition cost, to be determined by surveys of actual prices paid by physicians and other providers who dispensed these drugs. However, HCFA subsequently decided that this strategy was unworkable because of the large number of providers and the wide variations in their use of drugs and the prices paid. In the 1997 Balanced Budget Act, reference to estimated acquisition cost was deleted and AWP minus 5% became the sole basis for reimbursement.

The AWP has become a list price that is set by the drug's manufacturer and published by pricing services such as the Red Book. With AWP not defined in either statute or regulation and no requirements or conventions that AWP reflect actual market prices, the General Accounting Office (GAO) reflected consensus opinion when it concluded that AWP "may be neither average nor what wholesalers charge."[5,6] Some even translate AWP as "ain't what's paid." Studies by the GAO and the Department of Health and Human Services Office of the Inspector General have consistently concluded that this standard results in payment by Medicare that significantly exceeds providers' acquisition cost for most drugs and biologics, and excessive co-payments by beneficiaries, who pay 20% of the charge.[7] The physicians who administer Part B–covered drugs and are the chief beneficiaries of the spread between AWP minus 5% and their actual acquisition costs argue that overpayment is needed to compensate for inadequate Medicare payments for drug administration.[6] Whatever its empirical validity, this claim that overpayment for drugs makes up for inadequate physician fees kept Congress from reducing Part B drug payments until the MMA, which raised payments for selected professional oncology services.

Before dismissing an AWP-based approach, it is worth noting that many private sector payers, who are presumably motivated to minimize costs and who lack the statutory constraints faced by Medicare, also traditionally base their drug reimbursement to pharmacies on discounted AWP. The critical difference is that private payers apply a larger percentage discount and revise the percentage periodically, to capture most of the spread between AWP and the pharmacy's actual cost of acquiring drugs. Thus, the real questions are (1) could an AWP-based approach for Medicare be revised to eliminate its prior problems; (2) how does a revised AWP approach compare to using ASP or some other transactions price as the basis for reimbursement; and (3) will competitive bidding strategies provide a superior alternative?

## ECONOMIC FUNDAMENTALS OF REIMBURSEMENT FOR OUTPATIENT DRUGS

Sound payment policy for any medical service should provide reasonable cost control while creating incentives for efficient utilization. In the case of pharmaceuticals, sound payment policy must also consider effects on incentives for R&D. Given the cost structure of research-based pharmaceuticals, with high fixed costs of R&D and low marginal costs, the concern is that a large payer such as Medicare might use its monopsony (single buyer) power to force prices down to marginal cost, which would erode incentives for R&D. Because pharmaceutical R&D takes 8 to 15 years, the effect of inadequate prices on the flow of new drugs would not be evident until many years later, in contrast to inadequate prices for other medical services in which providers' withdrawal of services acts as a prompt corrective to inadequate prices.

So far, both Medicare and Medicaid have adopted reimbursement practices similar to those used by private payers, but with important differences. Both public and private payers overwhelmingly pay for drugs indirectly, reimbursing the dispensing pharmacist or physician for their cost of acquiring the drugs plus a dispensing fee, rather than paying manufacturers directly. A fundamental challenge in designing these reimbursement rules is that payers do not observe the acquisition costs paid by dispensing pharmacists and physicians, and these acquisition costs may vary, reflecting manufacturer discounts geared to volume, prompt payment, incentives to increase market share, and bundling. Any spread between the payer's reimbursement for the drug and its acquisition cost accrues as income to the dispensing pharmacy or physician, regardless of whether the payer's benchmark for reimbursement is AWP or some proxy of acquisition cost. Because each provider's actual acquisition cost is unobservable, the payer can at best hope to roughly approximate average acquisition cost, while having a neutral effect on prescribing and dispensing choices (unless the payer specifically wishes to influence usage, such as encouraging generic substitution).

The fact that providers capture some spread between reimbursement and acquisition cost of drugs is often viewed as inappropriate. In fact, such margins between reimbursement and cost may occur for all medical services. Although the payer may appear to pay too much in the short run, in the longer run the potential for providers to capture such margins reinforces their incentives to try to reduce their costs. Indeed, making providers cost-conscious, by giving them both upside and downside risk for costs, was a key objective in the switch from cost-based reimbursement to prospective payment for hospitals and physicians. In the case of drugs, permitting dispensers to capture some spread between reimbursement and acquisition cost creates incentives for them to be price-sensitive, which in turn leads drug manufacturers to compete by cutting prices.

Such competition can yield savings to payers, provided that manufacturers cannot simply increase the spread by raising the AWP and that payers reduce their payment to reflect lower acquisition prices. Many private payers take advantage of this system, reimbursing retail pharmacies based on AWP minus a percentage—now roughly 15% to 18%—that has increased over time as the spread has increased. Many Medicaid programs use a similar approach as at least 1 option for pharmacy reimbursement. Similarly, the key drivers of generic price competition in the United States are that pharmacies can substitute between approved generics and can capture the spread between the payer's reimbursement, usually a MAC and their acquisition cost. By making pharmacists price-sensitive, this system creates incentives for generic manufacturers to compete on the prices that they offer pharmacies, to increase their share of the pharmacy's business. Thus although the reimbursement spread may appear inappropriate, it serves the important potential function of encouraging price competition by manufacturers, which can yield savings to payers if reimbursement is adjusted down in line with costs.

An alternative approach is for the payer to define the permissible manufacturer price for the drug, adding a markup to cover wholesalers and dispensing costs. Countries that regulate drug prices generally apply this approach to regulating the manufacturer's price at launch. Price regulation uses 1 of 3 benchmarks: (1) the price of competitor products in the same class as the new drug (internal referencing); (2) the price of the

same drug in other countries (external referencing); or (3) some estimate of manufacturer costs. None of these approaches meets the criteria for sound payment policy to manufacturers. Internal referencing raises issues of appropriate markups for innovation or superior safety or efficacy, and for on-patent versus generic status; external referencing simply imports foreign price controls and undermines appropriate cross-national price differentials; and cost-based reimbursement for pharmaceuticals is doomed by problems of measuring and allocating joint cost.[8,9]

The hope of both the administered pricing rules and competitive contracting options proposed for Medicare is that these can constrain prices to reasonable levels while avoiding the opposing risks of forcing prices down to marginal cost or, alternatively, paying inappropriately high prices.

## MEDICARE PART B REIMBURSEMENT OPTIONS

We focus here on options for paying for Part B drugs as outlined in MMA; options for Part D would be similar. These options fall into 2 broad categories (Table). First, Medicare could define administered pricing rules, based on either a list price or an estimated transactions price, with discounts or markups. Any administered pricing rule could use internal reference pricing, whereby Medicare sets a single reimbursement level for all drugs in designated groups. Second, Medicare could use competitive bidding strategies, either contracting with manufacturers directly or indirectly, through pharmacy benefit managers (PBMs), PDPs, or health plans. Indirect contracting could encompass a range of possible services, from Part B drugs only to comprehensive health benefits.

### List Price With a Discount or Markup

A discounted list price approach, such as AWP minus 5% or 15%, has the obvious advantage that list prices are easily obtained from pricing services. A less obvious but key economic advantage is that this approach encourages price competition below the prevailing reimbursement level, as manufacturers seek to increase the spread to providers, as discussed above.

Two modifications of Medicare's traditional AWP-based strategy are necessary to make it attractive. First, Medicare should have the flexibility to adjust the discount over time to keep reimbursement roughly in line with acquisition costs, as determined by audit of market transactions, and enable Medicare to share in the savings from price competition. Second, the rate of increase in AWP should be constrained, for example, to the rate of increase in the consumer price index or producer price index from a predetermined date, or an excess-inflation penalty could be imposed. These modifications would reduce the potential for manufacturers to increase the spread by raising the list price rather than cutting the acquisition price.

An obvious disadvantage of any list price, including AWP, is that it may deviate substantially from actual transaction price. However, if transactions prices are monitored quarterly and the discount percentage

**Table 1.** Options for Medicare Part B Drug Reimbursement

| Administered Pricing Rules*,† | |
|---|---|
| **Price** | **Equation** |
| **List price** | |
| Wholesaler-level – discount | AWP – $x_1$% |
| Manufacturer-level + markup | WAC + $x_2$% |
| **Transactions price (estimated)** | |
| Wholesaler-level + markup | ASP + $x_3$% |
| Manufacturer-level + markup | ASP + $x_4$% |

| Competitive Contracting Strategies | | |
|---|---|---|
| **Type of Contracting** | **Contractor** | **What Is Covered** |
| Direct contracting | Manufacturers | Part B drugs |
| Indirect contracting | Specialty pharmacies/PBMs | Part B drugs |
| Indirect contracting | PBMs/health plans | Comprehensive outpatient drug benefit, including Part B drugs |
| Indirect contracting | Health plans | Comprehensive health benefit |

*Any of the administered pricing options could use reference pricing.
†The percentage mark-ups or discounts could differ, depending on the services covered.
ASP indicates average selling price; AWP, average wholesale price; PBMs, pharmacy benefit managers; WAC, wholesale acquisition cost.

adjusted to capture the spread for the payer, as occurs in the private sector, the resulting payment level would approximate transactions prices with a lag, and the audit burden would be less than under a transactions price approach. Of course, even if margins are appropriate on average, both positive and negative deviations are possible for individual products, which could distort prescribing choices. However, this is true for every administered pricing rule, whether based on list or transactions prices, and for diagnosis-related group reimbursement for hospitals and resource-based relative-value scales for physicians. As long as the rate of increase of list prices is constrained, differences in the spread across drugs should reflect differences in manufacturer price cuts, not in manipulation of the list price.

An alternative list price that appears to be more grounded in acquisition costs is the WAC. Some states already use WAC plus a markup as an option to reimburse pharmacies under Medicaid. The wholesale acquisition cost is a manufacturer catalogue price to wholesalers and is also published by pricing services such as First Data Bank. However, if Medicare were to adopt WAC as a basis for reimbursement, exactly the same incentives that have distorted AWP would apply to WAC: manufacturers would have incentives to raise the listed WAC and then to offer discounts below WAC to increase the provider's spread. Thus, any manufacturer-determined list price will face the same potential for distortion as AWP, unless constrained by an excess-inflation penalty.

Under a discounted AWP approach with consumer price index or producer price index constraints, regulations should clarify that selling below the list price should not be grounds for charges of fraud and abuse. Given the 2 provisions proposed here, that the increase in AWP is constrained and the payer captures the spread by adjusting the discount factor, then any margin between the AWP and the actual selling price can be presumed to reflect competitive discounting and is to be encouraged.

In general, reimbursement to physicians or pharmacies for dispensing costs is better done through a fixed dispensing fee, rather than by paying a percentage of the drug price. Dispensing and overhead costs usually do not vary with the price of the drug. Paying a percentage of the drug price encourages use of higher-priced drugs.

### Transactions Prices With Markups/Rebates

Setting reimbursement based on a transaction price plus a markup rather than a list price is intended to ground reimbursement more firmly on the provider's actual acquisition cost. With this objective in mind, starting on January 1, 2005, Medicare will pay for Part B drugs based on ASP plus 6% or a widely available market price. A drug's ASP is defined as the average sales price to all purchasers, excluding certain public purchasers, and is to be reported quarterly by manufacturers to CMS, with significant penalties for misreporting.

The fundamental concern with this approach is that it undermines manufacturers' incentives to compete on price. At the limit, if a reduction in price is perfectly matched by a reduction in reimbursement, the physician has no incentive to use the lower-priced drug and the manufacturer has no incentive to reduce price; rather, the manufacturer may have an incentive to raise price.

This tendency for ASP-based reimbursement, like any cost-based reimbursement, to lead to price increases may be attenuated by 2 factors. First, because reimbursement to all physicians is based on average sales price, not the physician-specific sales price, the manufacturer may still have an incentive to discount to highly price-sensitive physicians. However, this incentive is muted because ASP is a volume-weighted average price. Second, if private payers continue to reimburse physicians based on discounted AWP, then the incentive to raise prices to maximize reimbursement from Medicare patients may be constrained. However, given Medicare's dominant market share for most Part B drugs, the likely effect of ASP-based reimbursement is to reduce incentives for price competition, leading to higher prices to both private payers and Medicare than would occur under our proposed constrained-AWP-minus-X%, where X% is revised based on actual margins.

The manufacturer's incentives to discount would be slightly less under our proposed flexible discount off AWP rule, compared to the current fixed 5% discount off AWP, to the extent that manufacturers anticipate that a discount granted in period $t$ may lead to a larger reimbursement discount off AWP in $t + 1$. However, this negative effect on incentives to discount is weak because the reimbursement discount off AWP is an average over all products. By contrast, the negative effect on incentives to discount is much greater under the ASP rule, because each drug's ASP reimbursement in $t + 1$ depends on drug-specific discounts in period $t$.

A similar reduction in manufacturer discounts to private payers occurred after Medicaid's adoption of the Omnibus Budget Reconciliation Act of 1990, which required manufacturers to give a rebate to Medicaid equal to the greater of 15.1% of average manufacturer price (AMP) or AMP-"Best Price" to private buyers.[10,11]

### Reference Pricing

Administered pricing rules based on either list or transaction prices could be combined with internal ref-

erencing, whereby Medicare would set a single reimbursement for all drugs in the designated group.[8,12] Maximum allowable charge reimbursement for multisource drugs, as already used by Medicaid and many private payers, exemplifies generic referencing. We endorse the MMA's adoption of MAC reimbursement for multisource drugs under Parts B and D. Generic referencing offers significant cost savings to payers without significant health risk to patients or disincentive for R&D.

More controversial is therapeutic referencing, which applies the same reimbursement to different compounds in a therapeutic class—for example, all β-blockers—with the reimbursement level usually set at the lowest price in the class. Manufacturers may charge a price above the reference price, but the patient must pay the difference. The recent attempt by CMS to reimburse similar products (such as Procrit and Aranesp) at the same rate based on "functional equivalence" is therapeutic referencing in all but name. If applied to drugs that are equivalent in all relevant dimensions, then therapeutic referencing is consistent with cost-effectiveness principles; however, if applied without rigorous evidence, then therapeutic referencing may deny payment for real improvements in treatments, for at least some patients, and undermine incentives for research in such improvements. Of course, the difference between real improvements and minor variations is a fine line. However, such judgments should be based on empirical evidence, given their potential effects on incentives for innovation. The MMA prohibits the use of functional equivalence unless it was in place prior to the legislation's passage.

### Competitive Contracting for Medicare Part B Drugs

Competitive contracting approaches seek to avoid the need for Medicare to define administered pricing rules. Under a direct purchase approach, Medicare would procure drugs directly from manufacturers, as does the Department of Veteran's Affairs (VA). However, the VA direct procurement model is impractical for Medicare. The VA delivers services through its own, compact provider system. By contrast, Medicare uses the private sector delivery system, including thousands of private physicians and pharmacies who must be reimbursed for the drugs that they acquire and dispense.

Under indirect contracting for Part B drugs, as planned starting in 2006, Medicare will contract with specialty pharmacies, distributors, or PBMs to contract with manufacturers, negotiate prices and deliver drugs to physicians. Specialty pharmacies currently handle most Part B drugs that require special handling, such as patient-specific dosing and just-in-time delivery to physician offices; however, chain pharmacies and PBMs are increasingly entering this market. The MMA provisions for Part B drugs will thus provide a test—albeit a specialized one—of the indirect competitive contracting model for Medicare drug benefits.

Under the MMA indirect contracting approach, specialty pharmacy contractors for Part B drugs will be reimbursed for a drug at the lowest bid price of any contractor in the area, plus an administrative fee for drug handling and delivery. Contractors on Part B drugs are not authorized to engage in active formulary management and will not be at risk for total drug expenditures. Whether this indirect contracting approach, with contractors as passive administrators, can yield acceptable control over drug prices is far from certain. The leverage of private sector PBMs in negotiating discounts with manufacturers depends critically on their use of tiered formularies to shift market share to preferred drugs. If Part B drug contractors must offer a totally open formulary, undifferentiated by tiered copayments, manufacturers would have little incentive to offer price discounts except to the extent that the beneficiaries' 25% copayment creates some price-sensitivity of final demand. If a manufacturer offered discounts to a particular contractor, this might increase the likelihood that contractor would win the Medicare contract but would have no effect on patient or physician behavior and hence no effect on the manufacturers' market share.

Thus an indirect contracting model with specialty pharmacies/PBMs that lack discretion to design restrictive formularies is likely to be ineffective at stimulating price competition between manufacturers. Such manacled indirect contracting is likely to generate less competitive pressure on drug prices than a constrained-AWP-minus-X% administered pricing rule, which preserves manufacturers' incentives to cut prices to prescribing physicians while capturing much of the savings for Medicare, provided that the discount percentage is revised periodically.

In fact, if Medicare adopts indirect contracting with specialty pharmacies/PBMs but without formularies to control prices, Medicare would probably still have to define an administered pricing rule in order to determine reasonable reimbursement to the PBM contractors for the drugs they procure, if passive pass-through of drug prices is to be avoided. Similarly, competitive selection of intermediaries and carriers to administer hospital and physician services under Parts A and B has not relieved Medicare of the need to define administered pricing rules that these intermediaries apply in paying providers. An alternative reimbursement rule for

drugs would be to pay the lesser of the lowest indirect contractor price or constrained-AWP-minus-X%. Under this approach, Medicare could experiment with competitive contracting, but would be no worse off than under the revised AWP rule.

### Competitive Contracting for a Comprehensive Outpatient Drug Benefit

The MMA gives the PDPs some flexibility in formulary design for Part D drugs and places them at partial risk for Part D drug spending. Thus if administration of Part B is merged into Part D, the Part D formulary flexibility and associated incentives and ability to constrain prices may be extended to Part B. However, it remains uncertain whether PDPs will be willing to participate as risk-bearing contractors if they are required to offer open enrollment despite substantial adverse selection risk, have limited ability to constrain formularies and other aspects of benefit design, and are limited in their ability to raise beneficiary co-payments or premiums. However, if PDPs are constrained in benefit design or are only minimally at risk for part of the administrative fee, with drug costs largely passed through to Medicare, then Medicare may again resort to administered pricing rules in order to limit its expenditures to acceptable levels.

### Competitive Contracting for Comprehensive Health Benefits

While the viability and efficiency of a stand-alone Medicare drug benefit administered through competing PDPs remain highly uncertain, less doubt exists that competing health plans can bear risk for the comprehensive set of healthcare benefits, including outpatient and Part B drugs. Admittedly, the Medicare+Choice program has experienced slow growth and plan withdrawals over the past few years, for reasons that are beyond the scope of this report. A more promising model is the Federal Employees Health Benefit Plan, run by the Federal government for its own employees.

The advantages of competitive contracting for comprehensive health benefits, rather than contracting only for stand-alone pharmacy benefits, let alone for Part B drugs only, is that comprehensive contracting allows the government to harness the health benefit expertise of private insurers in an integrated, competitive bidding premium model that may, over time, create efficiencies and savings in both benefit costs and administration. Competitive contracting places private plans in the role of negotiating reimbursement for drugs and other medical services, eliminating the need for administered pricing rules by Medicare. By removing the silos associated with current Medicare funding, contracting for comprehensive health benefits may enhance incentives and opportunities for savings in hospital or physician services that may result from adding comprehensive drug coverage.

## CONCLUSIONS

We view contracting for comprehensive health benefits, including both comprehensive outpatient drug coverage and current Part B drugs, as the most attractive model. Contracting for specific services separately—hospitals, physicians, or prescription drugs—is problematic, because of the distorting incentive effects of silo reimbursement and because Medicare cannot avoid setting pricing rules, either directly or indirectly, if it must determine reasonable reimbursement to the intermediaries who administer the program. Not surprisingly, Medicare has tended to adopt administered pricing rules, as the least bad alternative compared with passive cost pass-through. A similar outcome seems likely if Medicare seeks to contract indirectly for Part B drugs and even the Part D drug benefit.

If administered pricing rules are to be used, the least problematic are those that pay a flexible discount off of a constrained list price, such as inflation-constrained AWP minus a discount percentage that is adjusted periodically. This discounted list price approach should create the strongest incentives for price competition by manufacturers and capture some of the resulting savings for Medicare, with a lag. Although basing reimbursement on a transactions price—such as MMA's ASP approach for Part B drugs—might seem more grounded in actual acquisition costs, this approach is likely to increase manufacturer prices for both private and Medicare patients.

Direct competitive procurement by Medicare is impractical. Indirect competitive bidding, using PDPs/PBMs to negotiate prices with drug manufacturers, is likely to be ineffective unless the intermediaries are empowered to use formularies with tiered copayments and can keep a share of discounts negotiated. If these intermediaries are reimbursed for drug costs and administration, without bearing significant upside or downside risk, then Medicare may resort to an administered pricing rule based on AWP or ASP, to evaluate the reasonableness of the prices that it pays for drugs.

Similar conclusions may apply to competitive contracting for the Part D benefit, although the Part D PDPs are more likely to be able to use restrictive formularies

and be at some financial risk, thus increasing their ability and incentives to constrain prices to acceptable levels. However, the viability of stand-alone PDPs remains uncertain. The efficiency of competitive contracting for both Parts B and D may improve by being combined. Under MMA, CMS was to report to Congress on the feasibility of merging Part B into Part D in January 2005 (report unreleased as of February 3, 2005). Although issues such as differing co-insurance requirements will still need to be resolved, the stakeholder role of physicians in Part B will likely diminish, assuming that the shift to a 15% discount off AWP and then to ASP-based reimbursement reduces physicians' incomes from dispensing Part B drugs.

Competitive contracting for comprehensive health benefits would reduce many of the problems encountered in contracting for stand-alone drug benefits. Medicare would not need to define administered pricing rules for drugs or for other services. And Medicare and beneficiaries would benefit from integration of services, rather than silo-based reimbursement and management of drugs and other medical services. The Medicare Advantage program, if more successful than the Medicare+Choice program, would resolve many of Medicare's problems of devising payment rules for drugs.

## REFERENCES


1. **Joint Economic Committee.** *Medicare Beneficiaries' Links to Drug Coverage.* Washington, DC: Joint Economic Committee; April 10, 2003:1-4. Available at: http://jec.senate.gov/_files/MedicareLinks.pdf. Accessed November 9, 2004.
2. **Iglehart JK.** Medicare and drug pricing. *N Engl J Med.* 2003;348:1590-1597.
3. **Medicare Payment Advisory Commission.** *Report to the Congress: Variation and Innovation in Medicare.* Washington, DC: MedPAC; June 2003:150-168. Available at: http://www.medpac.gov/publications/congressional_reports/June03_Entire_Report.pdf. Accessed November 9, 2004.
4. **Pennebaker G.** The rest of the AWP story. *Computer Talk.* 1998:6.
5. **Gencarelli DM.** Average wholesale price for prescription drugs: is there a more appropriate pricing mechanism? *NHPF Issue Brief.* 2002 Jun 7(775):1-19. Available at: http://www.nhpf.org/pdfs_ib/IB775_AWP_6-7-02.pdf. Accessed November 9, 2004.
6. **Scanlon WJ.** *Medicare Part B Drugs: Program Payments Should Reflect Market Prices.* Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives. Washington, DC: United States General Accounting Office; September 21, 2001. GAO publication GAO-01-1142T. Available at: http://www.gao.gov/new.items/d011142t.pdf. Accessed November 9, 2004.
7. **Office of the Inspector General, Department of Health and Human Services.** *Medicare Reimbursement of Prescription Drugs.* Washington, DC: Office of the Inspector General; January 2001. DHHS publication OE1-03-00-00310. Available at: http://oig.hhs.gov/oei/reports/oei-03-00-00310.pdf. Accessed November 9, 2004.
8. **Danzon PM, Ketcham JD.** Reference Pricing of Pharmaceuticals for Medicare: Evidence From Germany, the Netherlands and New Zealand. In: Cutler DM, Garber AM, eds. *Frontiers in Health Policy Research (National Bureau of Economic Research, Volume 7).* Cambridge, Mass: The MIT Press; 2004:1-54.
9. **Danzon PM, Towse A.** Differential pricing for pharmaceuticals: reconciling access, R&D and patents. *Int J Health Care Finance Econ.* 2003;3:183-205.
10. **General Accounting Office.** *Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom.* Washington, DC: United States General Accounting Office; January 12, 1994. GAO publication GAO/HEHS-94-29.
11. **Congressional Budget Office.** *How the Medicaid Rebate on Prescription Drugs Affects Pricing for the Pharmaceutical Industry.* Washington, DC: Congressional Budget Office; January 1996.
12. **Kanavos P, Reinhardt U.** Reference pricing for drugs: is it compatible with US health care? *Health Aff (Millwood).* 2003;22(3):16-30.


## CORRECTION

Due to an editing error, the axis label for Figure 1 in "Do the Incentives in 3-Tier Pharmaceutical Benefit Plans Operate as Intended? Results from a Physician Leadership Survey" (Shrank WH et al, *Am J Manag Care.* 2005;11(1): 16-22) was incorrect. The corrected figure appears here.